REMARKS

Applicants respectfully request entry of amendments to claims 1-3, 5, 7, 9-11, 13-16, 19, 20, 22-24, 26, 27, 29, and 31-33. Claims 17 and 18 have been canceled. Support for the amendments can be found throughout the specification, including paragraphs [0009], [0035], [0047], [0106], FIGS. 3A and 3B, and the originally filed claims and, therefore, do not add new matter.

Applicants submit that pending claims 1-16 and 19-34 are in condition for allowance, or are in better condition for presentation on appeal, and respectfully request that the claims as amended be entered.

Rejection Under 35 U.S.C. §112, Second Paragraph

Claims 1-25 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. As claims 17 and 18 have been canceled, the rejection as applied to these claims is rendered moot.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

The Office Action alleges, in pertinent part, that the phrase "the surface-enhanced Raman scattering signal" is unclear since "[t]here are two signals monitored, one before the second specific binding pair member is added and another signal is after binding. Which signal is meant for the signal recited in such newly added limitation." Respectfully, the Action seems ignore the meaning of the phrase in view of the specification.

As stated in Beachcombers, International, Inc. v. WildeWood Creative Products, Inc., 31 U.S.P.Q.2d 1653 (Fed. Cir. 1994) "[t]he operative standard for determining whether this requirement [112 second paragraph] has been met is 'whether those skilled in the art would understand what is claimed when the claim is read in light of the specification.'" For the sake of clarity, Applicants submit that the claim expressly states that the SERS signal at issue is generated by excitation of the first specific binding pair member associated with the SERS active particle or substrate. Further, the specification clearly recites that the SERS effect is associated with the first specific binding pair member when the first specific binding pair member is

positioned close to the SERS-active particle or surface (see, e.g., paragraph [0035]). As a result of contact between a first specific binding pair member, in such close proximity to the SERS-active surface, and a second specific binding pair member, the SERS signal associated with the first binding pair is changed, and this change, when detected, is indicative of binding between the first and second binding pair (paragraph [0032]). Therefore, in contrast to the allegation that there are two signals monitored, what is monitored is a change in the SERS effect associated with the first specific binding pair member.

Thus, the meaning of the phrase, when read in light of the specification, would be clear to one of skill in the art because the skilled artisan would know that only one signal is monitored; i.e., the SERS signal associated with the first specific binding pair member. As such, one of skill in the art would understand the metes and bounds of the term.

For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 U.S.C. §102

Claims 1-4, 6-11, 13-17, and 20 stand rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Tarcha et al.

Applicants traverse the rejection as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below. As claim 17 has been canceled, the rejection as applied to this claim is rendered moot.

The Office Action alleges, in pertinent part, that the cited reference teaches the elements as recited in the present claims, including that the "Tarcha method achieves the same purpose, as that of the present invention, which is to detect the SERS signal when the analyte interacts with the surface for inducing a surface-enhanced Raman light scattering", suggesting that Tarcha anticipates the claims "regardless of if there is a label or not". Applicants respectfully submit that using an equivalent standard for anticipation is incorrect.

Notwithstanding the amendment to the claims, as stated in Richardson v. Suzuki Motor Co. Ltd., 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989), using equivalents (i.e., "corresponding or virtually identical, especially in effect or function," Id. at 1921) to show anticipation is not pertinent under section 102. So the statement that "Tarcha method achieves the same purpose"

to support that Tarcha anticipates the claims "regardless of if there is label or not" is inapposite in view of the case law.

Nevertheless, the claims have been amended to recite "unlabeled first and second specific binding pair members." Review of Tarcha demonstrates that the cited reference does not teach a method of using Raman light scattering in the absence of a Raman-active label (see, e.g., col. 1, lines 17-25; col. 3, lines 36-39; col. 5, lines 67-67, line 68 to col. 6, line 1; col. 6, lines 15-16, lines 20-36, lines 46-49, lines 65-66; col. 7, line 3; col. 8, line 36; Examples 1-21; and independent claims 1 and 4). Further, when a binding partner is adsorbed to an SERS surface in the absence of a Raman-active label, Tarcha explicitly teaches that such adsorption "gave no discernible spectrum" (see, e.g., col. 7, lines 21-26; col. 19, lines 12-14, and FIG. 3). Moreover, in view of the evidence of record where the Action has implicitly expressed that Tarcha does not teach a method of detection where the binding partner is unlabeled, taken together, these facts demonstrate that the cited reference does not teach all of the elements as claimed.

As stated in Hybritech Inc. v. Monoclonal Antibody, Inc., 231 U.S.P.Q. 81 (Fed. Cir. 1986), "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention."

Therefore, because the instant claims recite unlabeled first and second specific binding pair members, and the cited reference does not teach this element, Tarcha et al. do not anticipate the claimed invention.

Failure of the prior art to meet every element of the claimed invention does not meet the standard under 102. For these reasons, Applicants respectfully request that the rejection be withdrawn.

Rejections Under 35 U.S.C. §103

Claim 12 stands rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Tarcha et al. in view of Fray.

Applicants traverse the rejection, as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation in the references themselves or in knowledge generally available to one of skill in the art, to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. And, finally the prior art reference (or references when combined) must teach all claim limitations. The teaching or suggestion and reasonable expectation of success must both be found in the prior art and not in Applicants' disclosure. (See M.P.E.P. §706.02(j)).

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings. Applicants further submit that, in fact, the cited references "teach away" from the present invention.

The Office Action alleges, in pertinent part, that Tarcha is silent with respect to teaching using lithium chloride as the chemical salt. The Action then provides Fray to cure the deficiency identified in the primary reference. However, review of Tarcha demonstrates that the reference does not teach unlabeled first/second specific binding pair members, an element presently recited in the claims. Further, as stated above, the primary reference teaches that when a binding partner is adsorbed to an SERS surface in the absence of a Raman-active label, that such adsorption "gave no discernible spectrum" (see, e.g., col. 7, lines 21-26; col. 19, lines 12-14, and FIG. 3).

Thus, one of skill in the art would only extract from such a teaching that Raman light scattering using binding pair member adsorption to a SERS surface **requires** a Raman-active label. As such, the reference does not teach the purpose of detecting interaction between a first unlabeled specific binding pair member and a second unlabeled specific binding pair member, and thus, the purpose of Applicants' invention could not be accomplished using the teachings of the cited reference. Therefore, the reference teaches away, since the impression left to the skilled artisan is that the product would not have the property sought by Applicants (i.e., detectable interaction between first/second binding pair members in the absence of a Raman-active label). In re Caldwell, 319 F.2d 254, 256, 138 U.S.P.Q. 243, 245 (CCPA 1963).

Further, as there is no suggestion or expectation of success regarding the detection of unlabeled first/second specific binding pair members, whether Fray teaches using lithium chloride is immaterial.

Again, the "teaching or suggestion **and** reasonable expectation of success must **both** be found in the prior art." (Emphasis added). One cannot simple use the Applicants' disclosure as a "blueprint" to reconstruct, by hindsight, Applicants' claim. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). Because there is neither the suggestion nor expectation of success that can be found in the cited art, no *prima facie* case of obviousness has been established.

Because the teachings of Tarcha would not result in a method of detecting interaction of unlabeled binding pair members when combined with the teachings of Fray, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Applicants submit that because there is no reasonable expectation of successfully achieving the invention as claimed, there is no motivation to combine the cited references, thus, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

Claim 21 stands rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Tarcha et al. in view of Gole et al.

Applicants traverse the rejection, as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings. Applicants further submit that, in fact, the cited references "teach away" from the present invention.

The Office Action alleges, in pertinent part, that Tarcha is silent with respect to teaching SERS active substrate as porous silicon substrate comprising impregnated metals. The Action then provides Gole et al. to cure the deficiency identified in the primary reference. However, review of Tarcha demonstrates that the reference does not teach unlabeled first/second specific binding pair members, an element presently recited in the claims. Further, as stated above, the primary reference teaches that when a binding partner is adsorbed to an SERS surface in the

absence of a Raman-active label, that such adsorption "gave no discernible spectrum" (see, e.g., col. 7, lines 21-26; col. 19, lines 12-14, and FIG. 3).

Thus, one of skill in the art would only extract from such a teaching that Raman light scattering using binding pair member adsorption to a SERS surface **requires** a Raman-active label. As such, the reference does not teach the purpose of detecting interaction between a first unlabeled specific binding pair member and a second unlabeled specific binding pair member, and thus, the purpose of Applicants' invention could not be accomplished using the teachings of the cited reference. Therefore, the reference teaches away, since the impression left to the skilled artisan is that the product would not have the property sought by Applicants (i.e., detectable interaction between first/second binding pair members in the absence of a Raman-active label). In re Caldwell, 319 F.2d 254, 256, 138 U.S.P.Q. 243, 245 (CCPA 1963).

Further, as there is no suggestion or expectation of success regarding the detection of unlabeled first/second specific binding pair members, whether Gole teaches metalizing substrates such as porous silicon for use in Raman scattering detection is immaterial.

Again, the "teaching or suggestion **and** reasonable expectation of success must **both** be found in the prior art." (Emphasis added). One cannot simple use the Applicants' disclosure as a "blueprint" to reconstruct, by hindsight, Applicants' claim. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). Because there is neither the suggestion nor expectation of success that can be found in the cited art, no *prima facie* case of obviousness has been established.

Because the teachings of Tarcha would not result in a method of detecting interaction of unlabeled binding pair members when combined with the teachings of Gole, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Applicants submit that because there is no reasonable expectation of successfully achieving the invention as claimed, there is no motivation to combine the cited references, thus, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

Claims 5, 22-28, 30, and 31-34 stand rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Tarcha et al. in view of Maine et al.

Applicants traverse the rejection, as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings. Applicants further submit that, in fact, the cited references "teach away" from the present invention.

The Office Action alleges, in pertinent part, that Tarcha is silent with respect to teaching immobilizing the first specific binding pair member/antibody on an immobilizing substrate. The Action then provides Maine et al. to cure the deficiency identified in the primary reference. However, review of Tarcha demonstrates that the reference does not teach unlabeled first/second specific binding pair members, an element presently recited in the claims. Further, as stated above, the primary reference teaches that when a binding partner is adsorbed to an SERS surface in the absence of a Raman-active label, that such adsorption "gave no discernible spectrum" (see, e.g., col. 7, lines 21-26; col. 19, lines 12-14, and FIG. 3).

Thus, one of skill in the art would only extract from such a teaching that Raman light scattering using binding pair member adsorption to a SERS surface **requires** a Raman-active label. As such, the reference does not teach the purpose of detecting interaction between a first unlabeled specific binding pair member and a second unlabeled specific binding pair member, and thus, the purpose of Applicants' invention could not be accomplished using the teachings of the cited reference. Therefore, the reference teaches away, since the impression left to the skilled artisan is that the product would not have the property sought by Applicants (i.e., detectable interaction between first/second binding pair members in the absence of a Raman-active label). In re Caldwell, 319 F.2d 254, 256, 138 U.S.P.Q. 243, 245 (CCPA 1963).

Further, as there is no suggestion or expectation of success regarding the detection of unlabeled first/second specific binding pair members, whether Maine teaches different assay formats comprising attaching antibody/antigen to a solid phase is immaterial.

Again, the "teaching or suggestion **and** reasonable expectation of success must **both** be found in the prior art." (Emphasis added). One cannot simple use the Applicants' disclosure as

a "blueprint" to reconstruct, by hindsight, Applicants' claim. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). Because there is neither the suggestion nor expectation of success that can be found in the cited art, no *prima facie* case of obviousness has been established.

Because the teachings of Tarcha would not result in a method of detecting interaction of unlabeled binding pair members when combined with the teachings of Maine, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Applicants submit that because there is no reasonable expectation of successfully achieving the invention as claimed, there is no motivation to combine the cited references, thus, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

Claim 29 stands rejected under 35 U.S.C. §103(a), as allegedly being unpatentable over Tarcha et al. in view of Maine et al, and further in view of Fray.

Applicants traverse the rejection, as it might apply to the amended claims, including claims dependent therefrom, for the reasons given below.

Applicants submit that because the cited references do not teach all the claim limitations, one of skill in the art would not be motivated to combine the reference teachings. Applicants further submit that, in fact, the cited references "teach away" from the present invention.

The Office Action alleges, in pertinent part, that Tarcha and Maine are silent with respect to teaching that the first specific binding pair is adsorbed on the metal particle in the presence of lithium chloride. The Action then provides Fray to cure the deficiency identified in the primary and secondary references. However, review of Tarcha and Maine demonstrate that neither reference teaches unlabeled first/second specific binding pair members, an element presently recited in the claims. Further, as stated above, the primary reference teaches that when a binding partner is adsorbed to an SERS surface in the absence of a Raman-active label, that such adsorption "gave no discernible spectrum" (see, e.g., col. 7, lines 21-26; col. 19, lines 12-14, and FIG. 3).

Thus, one of skill in the art would only extract from such a teaching that Raman light scattering using binding pair member adsorption to a SERS surface **requires** a Raman-active label. As such, the reference does not teach the purpose of detecting interaction between a first unlabeled specific binding pair member and a second unlabeled specific binding pair member, and thus, the purpose of Applicants' invention could not be accomplished using the teachings of the cited reference. Therefore, the reference teaches away, since the impression left to the skilled artisan is that the product would not have the property sought by Applicants (i.e., detectable interaction between first/second binding pair members in the absence of a Raman-active label). In re Caldwell, 319 F.2d 254, 256, 138 U.S.P.Q. 243, 245 (CCPA 1963).

Further, as there is no suggestion or expectation of success regarding the detection of unlabeled first/second specific binding pair members, the teachings of Maine and Fray are immaterial.

Again, the "teaching or suggestion **and** reasonable expectation of success must **both** be found in the prior art." (Emphasis added). One cannot simple use the Applicants' disclosure as a "blueprint" to reconstruct, by hindsight, Applicants' claim. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). Because there is neither the suggestion nor expectation of success that can be found in the cited art, no *prima facie* case of obviousness has been established.

Because the teachings of Tarcha and Maine would not result in a method of detecting interaction of unlabeled binding pair members when combined with the teachings of Fray, one of skill in the art would not have an expectation of success since the invention as claimed would not be achieved in view of such teachings. Therefore, one of skill in the art would not be motivated to combine such teachings.

Applicants submit that because there is no reasonable expectation of successfully achieving the invention as claimed, there is no motivation to combine the cited references, thus, no *prima facie* case for obviousness exists. For these reasons, Applicants respectfully request that the rejection, including as it might be applied against the amended claims, be withdrawn.

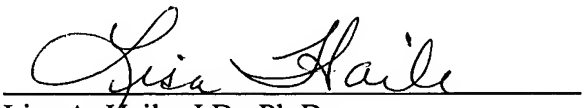
Conclusion

Applicants submit that pending claims 1-16 and 19-34 are in condition for allowance, or are in better condition for appeal. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this submission.

No fee is deemed necessary with the filing of this paper. However, the Commissioner is hereby authorized to charge any fees required by this submission, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number. A duplicate copy the Transmittal Sheet is enclosed.

Respectfully submitted,

Date: April 7, 2006



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